

Virginia Department of Health Guidance related to patient requests for personal stockpiles of oseltamivir (Tamiflu®)

As media attention to a possible influenza pandemic continues, citizens are asking their physicians to prescribe oseltamivir (Tamiflu) for personal stockpiles for possible later use during an influenza pandemic. The Virginia Department of Health (VDH) is not encouraging the practice of writing such prescriptions or the establishment of personal stockpiles. We recognize, however, that physicians may wish to consider the special circumstances of individual patients before making a decision about whether to honor these requests, and in those situations VDH offers the following guidance regarding the advantages and disadvantages of such prescribing.

Reasons to consider prescribing oseltamivir:

- Covers more than one type of influenza – oseltamivir is active against both Type A and Type B influenza.
- Prophylaxis or therapy – oseltamivir can be used for either prophylaxis against influenza infection or as therapy for established infection.
- May not prevent development of immunity – when used as prophylaxis, oseltamivir can prevent illness while permitting sub-clinical infection and development of protective antibody against circulating influenza viruses. Therefore, some persons who take these drugs will likely develop protective immune responses to circulating influenza viruses.
- In vitro effectiveness against avian influenza – this is the one antiviral medication that shows in vitro activity against the H5N1 strain of avian influenza now in Southeast Asia. This influenza strain now appears to be resistant to the earlier amantidine/rimantidine class of antiviral agents.
- Government stockpiles are limited – there is now a worldwide shortage of oseltamivir, with limited production capability at the present time. Although federal and selected state governments (including Virginia) are acquiring stockpiles of this medication, supplies would not be sufficient for the entire population, especially if a pandemic were to occur in the near future (within the next 12 months).

Problems with prescribing oseltamivir:

- Long duration may be required for prophylaxis – prophylaxis needs to be taken for at least as long as the period of peak influenza activity in a community. A pandemic may affect a community in several waves, further complicating prophylaxis. Additionally, to be maximally effective as prophylaxis, the drug must be taken each day for the duration of influenza activity in the community, not just the peak period. This makes use of oseltamivir as prophylaxis questionable and potentially very costly.

**Virginia Department of Health Guidance
related to patient requests for personal stockpiles of oseltamivir
(Tamiflu®)**

- Timing is critical when used as therapy – oseltamivir should be administered within two days of illness onset in order to have greatest effect on clinical course; this requires rapid, accurate diagnosis.
- Benefits may be limited when used as therapy – oseltamivir can reduce the duration of uncomplicated influenza illness by approximately one day, compared with placebo, in a typical influenza season. Data are limited regarding the drug's effectiveness in preventing serious influenza-related complications.
- Uncertain clinical effectiveness against avian influenza – it is not clear how clinically effective oseltamivir is against human avian influenza infection. Many of the Southeast Asian patients who died of avian influenza H5N1 were taking oseltamivir.
- Uncertain effectiveness against a new pandemic strain – if there is an influenza pandemic, we don't know if it will be caused by the present avian strain in Southeast Asia or a completely different strain that may or may not be sensitive to oseltamivir or other classes of influenza medications.
- Oseltamivir is expensive – it would be expensive to buy treatment courses for all members of a family, and insurance would almost certainly not cover a prescription with no immediate clinical indication. Most insurance plans would also be very unlikely to cover prophylactic use, especially if the practice becomes widespread.
- Limited supplies best used for containment overseas – in view of the worldwide shortage, the limited supply of oseltamivir could be better used by treating those with avian influenza infection, which could help prevent spread of the virus beyond those countries now impacted by human infection, all of which have been in Southeast Asia.
- Limited supplies best used for priority groups in U.S. – if there is a pandemic, it will be important to have enough oseltamivir available to treat healthcare providers who would maintain the healthcare system, and others essential to security of the US population. Wide scale distribution of medication that may or may not be used could limit the supply available to key healthcare and first responder providers, as well as those most likely to die of influenza infection.
- Inappropriate or widespread use may lead to resistance – people may use oseltamivir for inappropriate indications, such as upper respiratory infections, thereby limiting its availability for influenza, and possibly increasing the risk of influenza drug resistance. Widespread use of oseltamivir among patients with influenza could lead to resistant strains of flu, potentially making the drug useless.
- Personal stockpiles may get lost – people may not track where they store the oseltamivir, once again making it unavailable when needed.
- Oseltamivir has a limited shelf life – properly stored, it is only guaranteed for five years, yet no one knows when a pandemic will hit. Stockpiled drugs might pass their expiration date before a pandemic starts.
- Side effects may offset benefits – there also may be side effects that haven't yet come to light because the drug has not been widely used.

**Virginia Department of Health Guidance
related to patient requests for personal stockpiles of oseltamivir
(Tamiflu®)**

- Personal stockpiling as a strategy raises equity issues – at \$5 per pill, not everyone will be able to afford a personal stockpile; some will not even have access to a physician to get a prescription.
- Absence of consumer guidance – there are no good guidelines (or research to support such guidelines) for when people at home should take out a stock of medication and begin administering the drug to themselves or their families—this is venturing into ‘unknown territory.’

Recommended topics to cover in patient education if oseltamivir is prescribed:

- Clarification of goal of prescription – is it prophylaxis or treatment?
- Contraindications and potential drug interactions
- Recommendations regarding use during pregnancy
- Known side effects
- What will be the trigger to begin taking the medication and how will the trigger be recognized?
- How often and for how long should the medication be taken?
- Hazards of sharing medications with others
- Storage requirements
- Shelf life
- Proper disposal of expired medications